

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

NED S. RASOR et al.

Application No.: 09/614,389

Filed: July 12, 2000

For: METHODS AND APPARATUS  
FOR RELIEVING  
HEADACHES, RHINITIS AND  
OTHER COMMON AILMENTS

Customer No.: 20350

Confirmation No. 1930

Examiner: HENRY A. BENNETT

Technology Center/Art Unit: 3743

DECLARATION OF JULIA S. RASORAssistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

I, JULIA S. RASOR, declare as follows:

1. I am a co-inventor of the above-referenced patent application.  
2. This statement concerns the use of a CO<sub>2</sub> dispenser and nasal and/or oral and/or ocular administration method (which may be performed without inhalation of the treatment gas) for the treatment of allergic rhinitis, headache, and other indications and the disclosure to others of the use of the dispenser and method for those indications. The early use of the dispenser (around 1957-present) and method for treatment of allergic rhinitis and its disclosure to others are described in a separate statement by the inventor, Ned S. Rasor, which was previously submitted on November 17, 2003.

3. I began work in December, 1998, on the CO<sub>2</sub> dispenser and method for treatment of allergic rhinitis invented by Ned S. Rasor. From that time to the time the first provisional patent application was filed in July 1999, I do not recall any instance when I disclosed such use without a written nondisclosure agreement (NDA) other than to immediate family members (who used it privately in their home or in the inventors' homes under the supervision or control of one of the inventors), to attorneys as attorney-client privileged information (John I. White, Hubert E. Dubb, Ronald Fish, James M. Heslin), and to the first angel investor in what was to become CAPNIA, Inc., Timothy J.

Mark (who was shown it by one of the inventors in the inventor's home with the clear understanding that the device and method were to be kept secret). Also, I knew that Ned S. Rasor allowed Billy Joe Patton, an employee who lived with him, to use the device to treat his allergic rhinitis privately in their home under his supervision with the clear understanding that the device and method were to be kept secret. In addition, the inventors took care not to disclose any details regarding the dispenser design (e.g., needle configuration) or method of dosing (e.g., gas flow rate) even to those nine people who signed an NDA.

4. At the time I began work on the CO<sub>2</sub> dispenser and method, to my knowledge only three people had used the device. These were the inventor, Ned S. Rasor, and his wife both of whom had used the dispenser and method for approximately 40 years privately for their personal use to treat allergic rhinitis, and, in recent years (around 1996-1997) Billy Joe Patton. As stated above, Mr. Patton was informed that the device was secret and information regarding the device was not to be disclosed to anyone.

5. Prior to my work on the CO<sub>2</sub> dispenser, no dosing regimen had ever been specified or quantified. Therefore, I initiated private feasibility experiments in order to test the dispenser and method efficacy and to specify and quantify a dosing regimen for allergic rhinitis. These experiments were conducted between April 1999 and April 2000. The subjects of these experiments were members of my immediate family, Billy Joe Patton, and, for one test performed after the July 1999 provisional patent application, Martin E. Sanders, M.D., a potential investor who subsequently became a member of CAPNIA's Medical Advisory Board and signed an NDA. All the tests were performed in the subject's home, where employed, or in the inventors' homes. All tests were conducted in private settings and all tests were conducted under the supervision or control of one or both of the inventors. We made it clear to all test subjects that our use of CO<sub>2</sub> was confidential and proprietary and that they were to keep their involvement secret.

6. After completion of the experiments, Ned S. Rasor, immediate family members, and Billy Joe Patton continued to use the device and method privately to treat allergic rhinitis. There are only two or three dispensers in use at any one time and these are used only in the inventors' homes such that the inventors retain complete control over their use to benefit from the experience in such use. All experimental subjects were

made aware of the proprietary nature and confidentiality of the device and its application and, to my knowledge, have not disclosed any such information.

7. From July 1999, when the provisional patent application was filed, to the present, no details regarding the dispenser design, method of dosing, or clinical data for allergic rhinitis have been disclosed without an NDA except to attorneys as attorney-client privileged information. (J. Casey McGlynn, Robert Brownell, Mark J. Casper, Jill L. Robinson, and Mark A. Haynes). In addition, care was taken to only disclose details regarding devices and methods to those who needed to know (e.g., potential contract designers, manufacturers, and/or investors) who signed an NDA. *NRK 10-12-04*  
*Deleted for Julia Rawson request.*

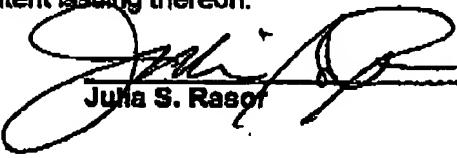
8. Around May-June 1999, after researching possible mechanisms of action of the nasal administration of CO<sub>2</sub> for relief of allergic rhinitis, I came to believe that the nasal administration of CO<sub>2</sub> also would be effective treatment for headaches (as well as other conditions). I began feasibility experiments in August 1999 which are described in more detail below. The results of these experiments appeared to confirm the dispenser and method developed for allergy relief could be used for relief of headache.

9. From May-June 1999 to the time the first provisional patent application was filed in July 1999, I do not recall any instance when I disclosed the use of the dispenser or method for headache or disorder other than allergic rhinitis without an NDA other than as privileged information to immediate family members (who used it privately in their home or in the inventors' homes under the supervision or control of one of the inventors), to an attorney as attorney-client privileged information (James M. Heslin), and to the first angel investor in what was to become CAPNIA, Inc. Timothy J. Mark (who used it for headache relief, under supervision or control of one of the inventors, privately in his home, in the inventors' homes, or in a private room where employed with the clear understanding that the device and method were to be kept secret). In addition the inventors took care not to disclose any details regarding the dispenser design (e.g., needle configuration) or method of dosing (e.g., gas flow rate) even to those nine people who signed an NDA.

I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10-9-04

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Julia S. Raso